

Rec'd PCT/PTO 28 JAN 2005 #2

PCT U03/00960



REC'D 14 AUG 2003

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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002951773 for a patent by AG-ID PTY LTD as filed on 02 October 2002.

WITNESS my hand this
Fifth day of August 2003

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PROVISIONAL SPECIFICATION

Invention Title: "Sampling Device"

The invention is described in the following statement:

"Sampling Device"

Field of the Invention

The present invention relates to a sampling device and a method for its use. More particularly, the device and method of the present invention are intended for use in the simultaneous tagging of an animal and the collection of a biological sample therefrom.

Background Art

There has long been the need for those associated in animal related industries (including the breeding of livestock, show animals, racing animals and other thoroughbreds) to be able to accurately identify individual animals, either for the purpose of authenticating the animal itself or for identifying the source of animal products and samples. Some of the more commonly used techniques include branding, tattooing, ear tags, ankle straps, chains and transponders, either injectable or on tags or straps. All of these techniques have different costs and success rates associated with them.

The biological analysis of animals is important in many fields of endeavour including medicine, research, breeding, quality control and environmental technologies. It is well known that animals may be identified by DNA analysis. Identification generally involves removal of a sample from the animal and "off-site" laboratory analysis of the sample. Recent cases of infected or contaminated meat products has increased the need to be able to sample large numbers of animals and accurately associate each sample with its source. Furthermore, there is also the need to be able make this association difficult to break so that the source of samples can be correctly identified.

Modern DNA analysis can be performed on very small samples and can be conducted very quickly. Presently, quality control of biological material and the preparation of genetic genealogy of animals are conducted to an increasing degree with huge numbers of samples. DNA analysis is very sensitive and

impurities must be excluded. Furthermore, there is need to protect samples from DNA-degrading enzymes.

There are many ways of obtaining a sample of DNA from animals. For example, taking samples for DNA analysis can involve blood sampling. A skilled practitioner, for example, a vet, is needed for this method of sampling which can become very expensive, especially for large populations.

In cattle breeding, it is known to remove hairs and hair roots and place them into a sample container which is then labelled manually to identify the source of the biological material. This process can be time consuming and there are a number of potential problems that are particularly related to the degree of training of the sampler. These include the potential for falsification of samples either intentionally or accidentally. Intentional falsification may include the deliberate mislabelling of a sample or placing a sample from one source into a sample container that identifies the sample as having being sourced from a different animal. The above examples of falsification can also occur accidentally.

There is a need for a sampling device that is able to simultaneously register an animal (e.g. provide an identification means such as an ear tag) and take a sample of tissue for analysis whilst providing a sample container that minimizes the potential for intentional or accidental falsification of samples.

The sampling device of the present invention has one object thereof to overcome substantially, or at least provide an alternative to, the above-mentioned problems associated with the prior art.

The preceding discussion of the background art is intended to facilitate an understanding of the present invention only. It should be appreciated that the discussion is not an acknowledgement or admission that any of the material referred to was part of the common general knowledge in Australia as at the priority date of the application.

Throughout the specification, unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

Disclosure of the Invention

In accordance with the present invention there is provided a sampling device comprising a sample container and a tag means, wherein the tag means has both a receiving portion and an engagement portion, the sample container being adapted to positively engage the receiving portion, whereby the removal of the sample container from the receiving portion requires the compromise of the integrity of the sample container.

Preferably, the sample container is provided in the form of a tubular member.

The sampling device preferably further comprises a first ring adapted to provide an interference fit with an outer surface of the sample container. The first ring is preferably provided with an internal chamfer. The sampling device preferably further comprises a second ring adapted to provide an interference fit with the outer surface of the sample container. The second ring is preferably provided with an internal chamfer.

The sample container may be composed of a polymeric material substantially resistant to attack by solvents and biological samples. The sample container is preferably composed of polypropylene.

Preferably, the first ring and second ring are composed of a polymeric material susceptible to attack by solvents. In particular, it is preferable that they are susceptible to attack by dichloromethane. Preferably, the first and second rings are comprised of a hard, UV resistant plastic.

Preferably, the sample container is adapted to slidably receive the first ring wherein the first ring provides an interference fit with the sample container.

Further preferably, the sample container is adapted to slidably receive the second ring wherein the second ring provides an interference fit with the sample container.

Preferably, the first and second rings form a shoulder on the sample container.

Preferably, the tag means receiving portion has provided therein a base portion and a recess, wherein the recess is a substantially cylindrical portion and is adapted to receive the sample container. Preferably the recess further comprises an annular ridge extending into the recess.

Preferably, the recess has provided therein a means for positive engagement. The means for positive engagement may be provided in the form of three wedge shaped teeth.

Preferably, there is provided within a portion of the lower surface of the recess a stamped portion, adapted to be punched out of the lower surface. Preferably, the stamped portion is adapted to be punched out by a sample removal means.

The stamped portion may be provided with a bridge connecting the stamped portion of the lower surface to the remainder of the lower surface.

Preferably, the tag means receiving portion has provided therein at least one external shoulder.

Preferably, the engagement portion has provided therein a base member, a first shaft member, an annular member and a second shaft member wherein the second shaft member of the engagement portion is adapted to slidably receive the sample removal means.

Preferably, the sample removal means is provided in the form of a substantially hollow cylinder adapted to slidably engage the second shaft member and comprises a base member arranged substantially perpendicular to the cylindrical

axis of the sample removal means disposed at some distance along the length of the sample removal means such that it comprises an "H-shape" in cross-section.

Preferably, the sample removal means comprises an upper end and a lower end. The upper end may have provided thereat sharpened edges and is adapted to act as cutting means.

In accordance with a first embodiment of the present invention there is, within the upper end of the sample removal means, provided a breakable seal means defining within the upper end of sample removal means a sample receiving chamber. A sample preparative is preferably provided within the sample receiving chamber.

The sample removal means is preferably adapted to provide an interference fit in the sample container.

Preferably, the base member of the sample removal means is adapted to provide a seal in the sample container that is substantially fluid impermeable.

Preferably, the tag means is adapted to act as an ear tag for an animal and is formed of a polymeric material.

Preferably, the sample container is adapted to be able to move within the receiving portion recess. The amount of movement is preferably less than the combined widths of the first and second rings.

Preferably, removal of the sample container from the receiving portion does not remove the rings from the recess. The rings are prevented from being removed from the recess by the steps of the teeth. If the sample container is removed from the receiving portion, it is preferable that it cannot be re-inserted.

Preferably, the sample container is provided with a means of identification to indicate the source of the sample. The means of identification is preferably either a 2-dimensional means, including any one or more of a number and/or letter code,

and a bar code, or a printable RF code. Preferably, any attempt to alter the identification means results in damage to the means. Said damage is preferably able to be observed or recognised.

Preferably, the tag means is provided with a means of identification to indicate the source of the sample. The means of identification is preferably in accordance with that applied to the sample container. In one form of the invention, the tag means identification means is provided on the receiving portion of the tag means. Preferably any attempt to alter the identification means results in damage to the means. Said damage is preferably able to be observed or recognised.

Preferably, the sample container identification and the tag means identification impart the same information. Preferably, different information is provided by the identification means of different sampling devices.

In accordance with a second embodiment of the present invention the upper end of the sample removal means has provided therein an insert. The insert may have a peripheral upper edge chamfered to form in part the sharpened edge of the sample removal means.

The insert preferably seats on an internal shoulder adjacent the upper end of the sample removal means.

In one form of the invention the insert is provided with a base that defines therein a plurality of apertures, whereby animal tissue forced into contact therewith will be forced at least in part, through the apertures and into the sample receiving chamber. This action preferably mashes or pulverises the tissue to some extent.

The insert is preferably provided with at least a portion thereof raised to a peak to accentuate the tissue penetrative capacity of the insert.

The sample preparative may be provided in the form of rock salt.

Brief Description of the Drawings

The present invention will now be described, by way of example only with reference to two embodiments thereof and the accompanying drawings, in which:-

Figure 1 is an exploded cross sectional view of a sampling device in accordance with a first embodiment of the present invention;

Figure 2 is an upper perspective view of the receiving portion of the tag means of the sampling device of Figure 1;

Figure 3 is an upper plan view of the receiving portion of the tag means of the sampling device of Figure 1;

Figure 4 is a lower plan view of the receiving portion of the tag means of the sampling device of Figure 1;

Figure 5 is an upper perspective view of the sample removal means of the engagement portion of the sampling device of Figure 1;

Figure 6 is a cross sectional view of the sample container and the receiving portion of the sampling device of Figure 1;

Figure 7 is a cross sectional view of the engagement portion and the sample removal means of the sampling device of Figure 1;

Figure 8 is a cross sectional view of the sample container and the sample removal means of the sampling device of Figure 1;

Figure 9 is a cross sectional view of the engagement portion and the receiving portion of the sampling device of Figure 1;

Figure 10a is a cross sectional view of the sample container of the engagement portion of the sampling device of Figure 1;

Figure 10b is a cross sectional view of the sample container and first ring of the engagement portion of the sampling device of Figure 1;

Figure 10c is a cross sectional view of the inverted sample container, first ring and second ring of the engagement portion of the sampling device of Figure 1;

Figure 10d is a cross sectional view of the inverted sample container, first ring and second ring of the engagement portion of the sampling device of Figure 1;

Figure 11 is a plan view of an insert for use in a sample removal means of a sampling device in accordance with a second embodiment of the present invention; and

Figure 12 is a cross sectional exploded view of the sample removal means of a sampling device in accordance with a second embodiment of the present invention.

Best Mode(s) for Carrying Out the Invention

In Figures 1 to 10 there is shown a sampling device 10 in accordance with a first embodiment of the present invention, the sampling device 10 comprising a sample container 12, a first ring 16, a second ring 18 and a tag means 20.

The sample container 12 is provided in the form of a tube having an open end 22 and a closed end 24. The first ring 16 is provided with an internal chamfer 28 which forms an underside portion 29. The second ring 18 is provided with an internal chamfer 30 which forms an underside portion 31.

The tag means 20, best seen in Figure 1, comprises a receiving portion 32 and an engagement portion 34. The receiving portion 32 comprises an inner surface 36, an outer surface 38 and a recess 40. The inner surface 36 has provided thereon, substantially adjacent an open end 41 of the recess 40, a means for positive

engagement, for example three wedge-shaped teeth 42; best seen in Figures 1 and 2. The teeth 42 extend away from the open end 41 and project into the recess 40. The teeth 42 terminate in steps 46. An annular ridge 48 extends into the recess 40 from the inner surface 36 and defines therein a cylindrical portion 50. The outer surface 38 of the receiving portion 32 comprises a base member 52 and a shoulder 54. The base member 52 has centrally located thereon a stamped disc 56 and a bridge 58, best seen in Figure 4. The bridge 58 is substantially solid and is integrally formed with both the base member 52 and the disc 56, the junction of the base member 52 and the disc 56 being thinner and weaker than both the base member 52 and the bridge 58.

The engagement portion 34 comprises a base 60, a first shaft member 62, a frusto-conical member 64 and a second shaft member 66 having an upper end 68, best seen in Figure 7. The member 64 is of smaller diameter adjacent the second shaft member 66 and widens towards the first shaft member 62.

A sample removal means 70 is further provided and is adapted to slidably engage the second shaft member 66. The sample removal means 70 is provided in the form of a substantially hollow cylinder 72, with a base member 74 substantially perpendicular to the longitudinal axis of the cylinder 72 disposed at some distance from a lower end 76 such that it forms an "H-shape" in cross section, best seen in Figures 1, 7 and 8. An annular cutting edge 78 is provided at an upper end 80 of the cylinder 72.

Within the upper end 80 of the sample removal means 70, spaced some distance from the cutting edge 78, is provided a seal means, for example a wax-paper seal 81. The seal 81 extends across the full bore of the sample container means 70 and defines, with the base member 74, a sample receiving chamber 82. The seal 81 is provided in a breakable form by way of scoring or some other suitable means.

The sample receiving chamber 82 has provided therein an amount of sample preparative or preservative, for example Proteinase K in powdered form. This

powder may be provided free within the chamber 82 or may be located in a well (not shown) provided in an upper surface of the base member 74.

The sample container 12 and the sample receiving portion 32 are both labelled (not shown) to identify the source of the sample to be taken. For example, the label may comprise a series of numbers and/or letters that serve to identify an animal. The label cannot be removed without damaging the sample container 12 or the receiving portion 32. Any sampling device with a damaged sample container 12 or tag means 20 will not have a sample taken with it analysed.

To assemble the sampling container 12 for use, series of steps best seen in Figure 10 and described below are carried out. The sample container 12 is held with its open end 22 uppermost, as is best seen in Figure 10a. The first ring 16 is placed over the open end 22 with its internal chamfer 28 facing downwards and away from the sample container 12, best seen in Figure 10b. The first ring 16 provides an interference fit with the sample container 12.

The sample container 12 is inverted (Figure 10c) and a small amount of dichloromethane (not shown) applied to the underside portion 29 of the first ring 16. The second ring 18 is inserted over the bottom end 24 of the sample container 12 such that its internal chamfer 30 is facing downwards and away from the sample container 12 and slid along the sample container 12 until it abuts the first ring 16, best seen in Figure 10c. The first ring 16 and the second ring 18 are caused to fuse together due to the melting of small amounts of them by the dichloromethane. The fusing of the first ring 16 and the second ring 18 causes the formation of a shoulder 84 on the sample container, best seen in Figure 10d. The dichloromethane does not melt the sample container 12.

The sample container 12 is inserted into the receiving means recess 40 shouldered end first until the first ring 16 abuts the ridge 48, best seen in Figure 6. The annular step 46 prevents removal of the first ring 16 and second ring 18. If the sample container 12 is removed from the recess 40, the first and second rings, 16 and 18 respectively remain in the recess 40. Any attempt to re-insert the sample container 12 will be unsuccessful. Any sample container 12 that shows

visible signs that it has been separated from the receiving portion 32 prior to collecting a sample will not have its contents analysed.

The means of identification on the sample container 12 and the receiving portion 32 indicate the same sample source.

In further preparation for use, the sample removal means 70 is positioned over the second shaft member 66 of the engagement portion 34 until the base member 74 abuts the upper end 68 of the second shaft member 66, best seen in Figure 7.

A user (not shown) wishing to sample tissue from an animal and place a tag thereon fits the receiving portion 32 with the sample container 12 attached to a first part of a sampling and tagging gun (not shown). Similarly, the engagement portion 34 is fitted to a second part of the sampling and tagging gun (not shown). The first and second parts of the sampling and tagging gun are positioned adjacent to and on opposing sides of the tissue to be sampled and tagged, for example, an animal ear (not shown).

Activation of the sampling and tagging gun causes the engagement portion 34 and the receiving portion 32 of the tag means 20 to be brought towards each other. The sample removal means 70 punches an aperture in the ear. The tissue sample punched out in this manner bears upon the wax-paper seal 81 causing it to break. The seal 81 is then pushed aside by the tissue sample as it pushes into the chamber 82 where the sample contacts the sample preparative located therein.

The sample removal means 70, with the entrained tissue sample, then punches through the stamped disc 56 of the receiving portion 32. The bridge 58 prevents the stamped disc 56 from entering the cavity 72. The stamped disc 56 remains in the recess 40 of the receiving portion 32. The sample removal means 70 and the engagement portion 34 continue into the recess 40 of the receiving portion 32. The sample removal means 70, along with the second shaft member 66, continues into the sample container 12.

Movement of the projecting member 64 through the recess 40 to abut the sample container 12 causes the sample container 12 to be pushed out of the recess 40 of the receiving portion 32. The sample removal means 70 and the second shaft member 66 enter the sample container 12. They continue into the sample container 12 until the projecting member 64 abuts the sample container 12 as the projecting member 64 is too large to enter the sample container 12. Further movement of the projecting member 64 causes the sample container 12 to be removed from the receiving portion 32.

The sample removal means 70 provides an interference fit with the sample container 12 that is tighter than the fit of the sample removal means 70 and the second shaft member 66. The sample removal means 70 remains in the sample container 12 and the base member 74 provides a seal thereto that is substantially fluid impermeable. The sample container 12 and the tissue sample enclosed therein are able to be transferred for analysis, safe in the knowledge that the identification on the sample container 12 and the tag means 20 are the same.

Once the projecting member 64 has gone past the second ring 18, it is not able to be retracted from the recess 40 and hence the engagement portion 34 and the receiving portion 32 cannot be separated. A portion of the first shaft member 62 remains in the aperture formed in the ear. The engagement portion 34 and the receiving portion 32 collectively form the ear tag.

It is envisaged that the sample removal means 70 may be marked/printed within the lower end 76 thereof. This may require some modification of the lower end 76 to facilitate printing thereon. It is envisaged that the marking of the sample removal means 70 may alleviate the need to mark the sample container 12.

In Figures 11 and 12 there is shown a sample removal means 100 in accordance with a second embodiment of the present invention. The sample removal means 100 is similar to the sample removal means 70 and like numerals denote like parts.

The upper end 80 of the sample removal means 100 has an internal shoulder 102 provided adjacent thereto. An insert 104 is receivable within the upper end 80 and seats on the internal shoulder 102. The insert has a peripheral upper edge 106 chamfered to form in part the sharpened cutting edge 78.

The insert 104 is provided with a base 108 comprising a number of radial ribs 110 thereby defining a plurality of apertures 112. The ribs 110 are formed with a peak 114 at their intersection, best seen in figure 12.

In use, the sample removal means 100 is used in a manner similar to the sample removal means 100, although the animal tissue forced into contact therewith during the tagging operation will be forced, at least in part, through the apertures 112 and into the sample receiving chamber 82. The peak 114 accentuates the tissue penetrative capacity of the insert 104. The tissue passing into the chamber 82 will be somewhat mashed or pulverised by this process.

The sample receiving chamber 82 has an amount of rock salt provided therein as sample preparative or preservative due to its hygroscopic properties. The grain size of the rock salt allows its retention within the chamber 82 despite the apertures 112 of the insert 114.

While advantageous and preferred embodiments of the present invention have been selected and described as illustrations of the invention, it should be understood by those skilled in the art that changes and adaptations can be made therein without departing from the scope of the invention.

Dated this Second day of October 2002.

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Applicant

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Perth, Western Australia
Patent Attorneys for the Applicant(s)

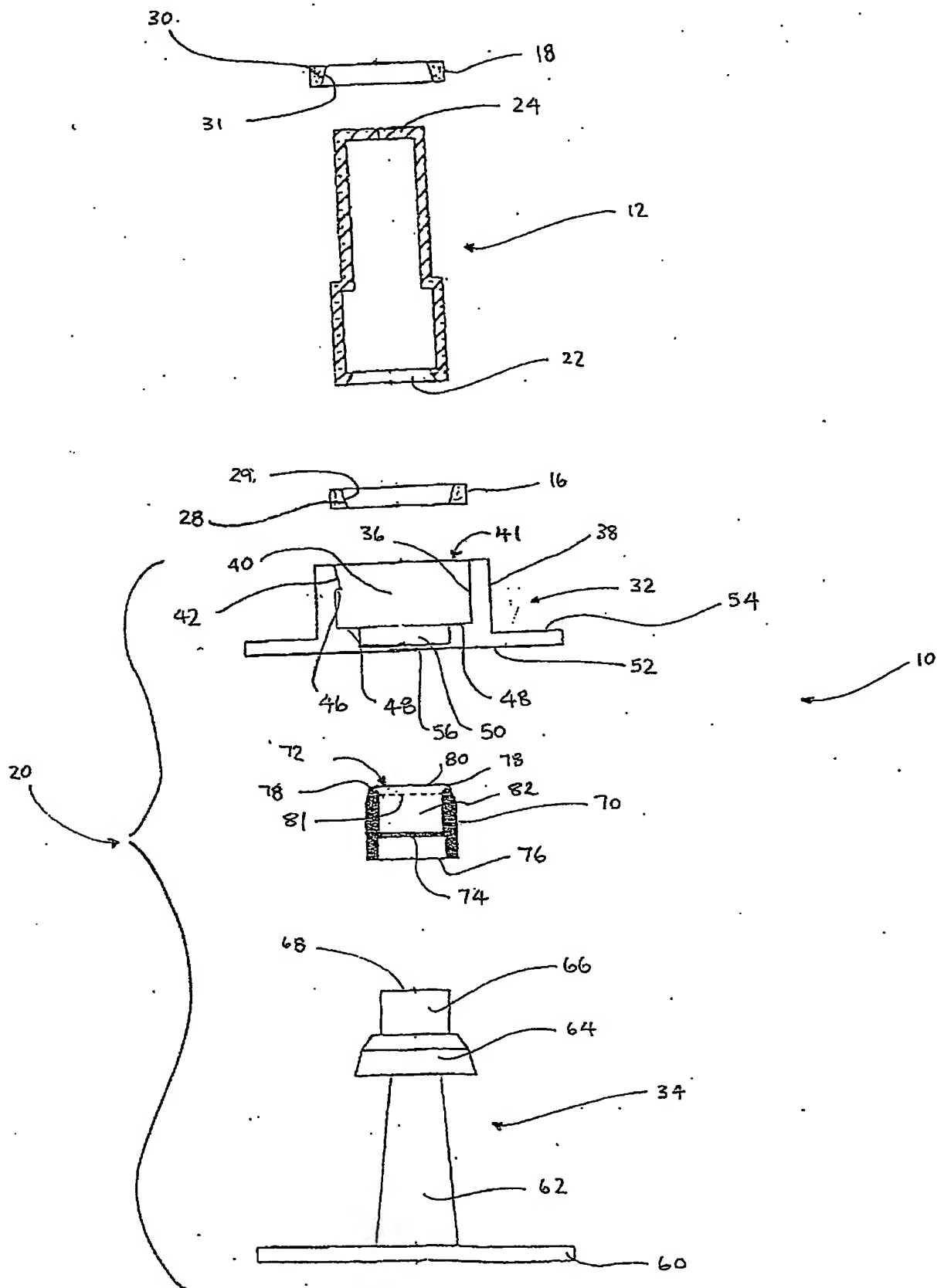


Figure 1

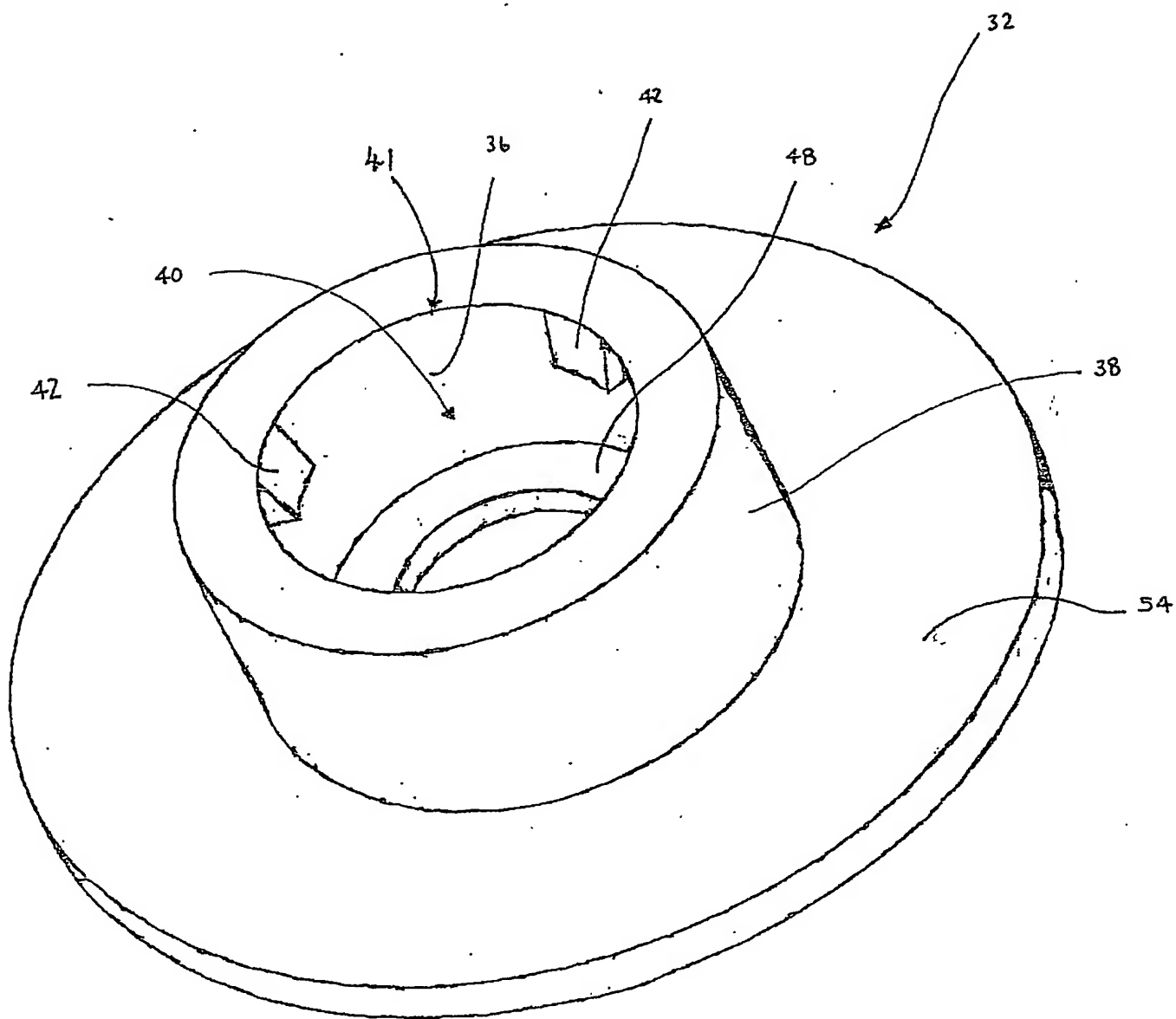


Figure 2

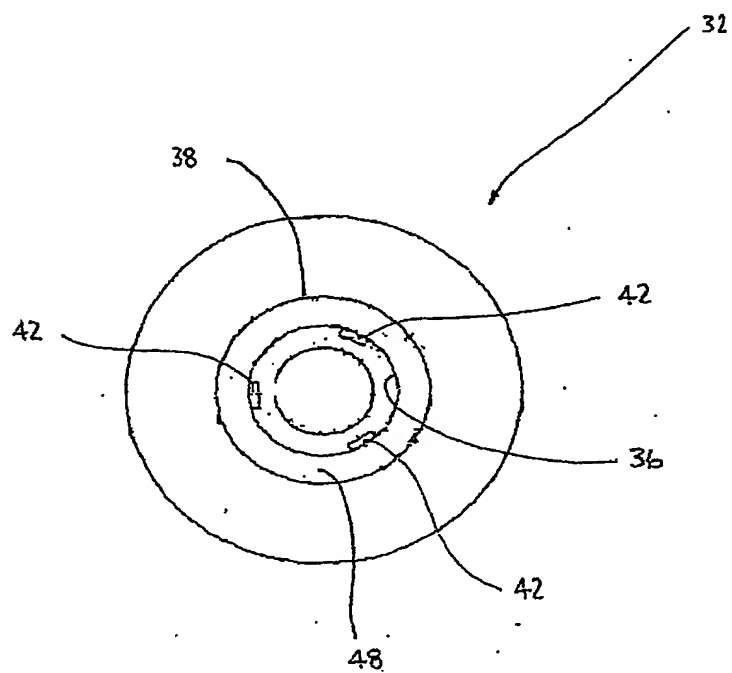


Figure 3

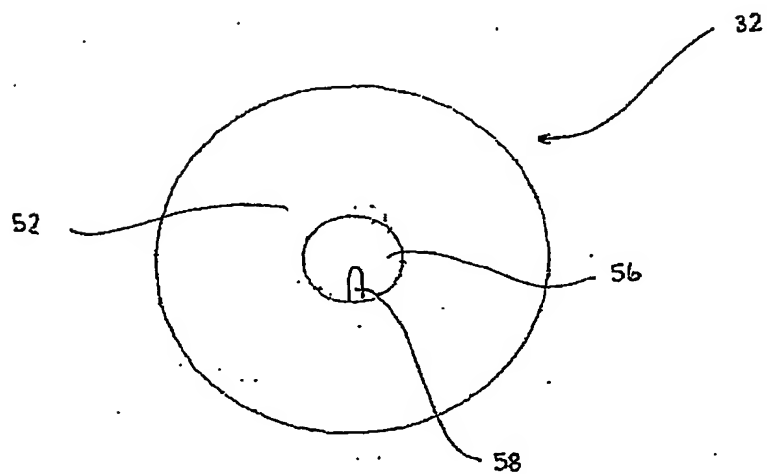


Figure 4

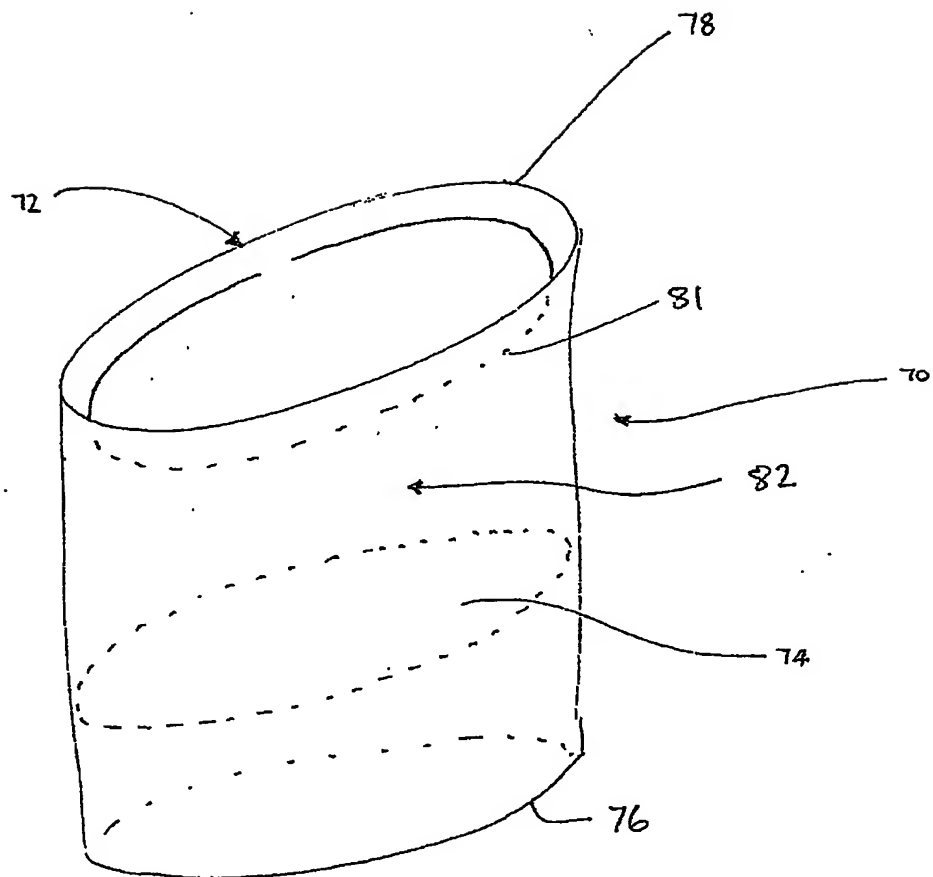


Figure 5

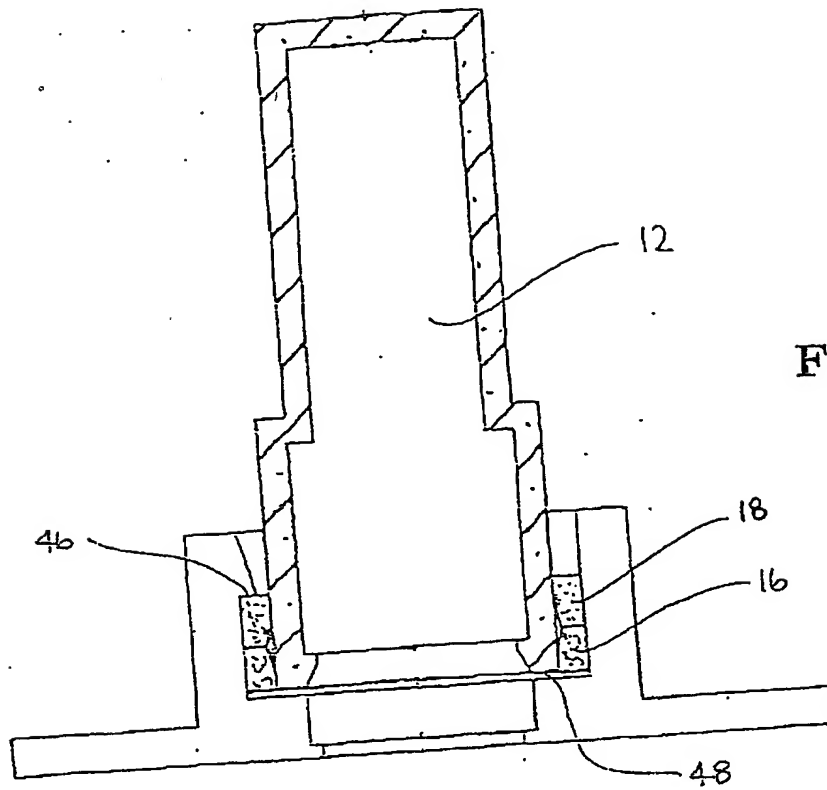


Figure 6

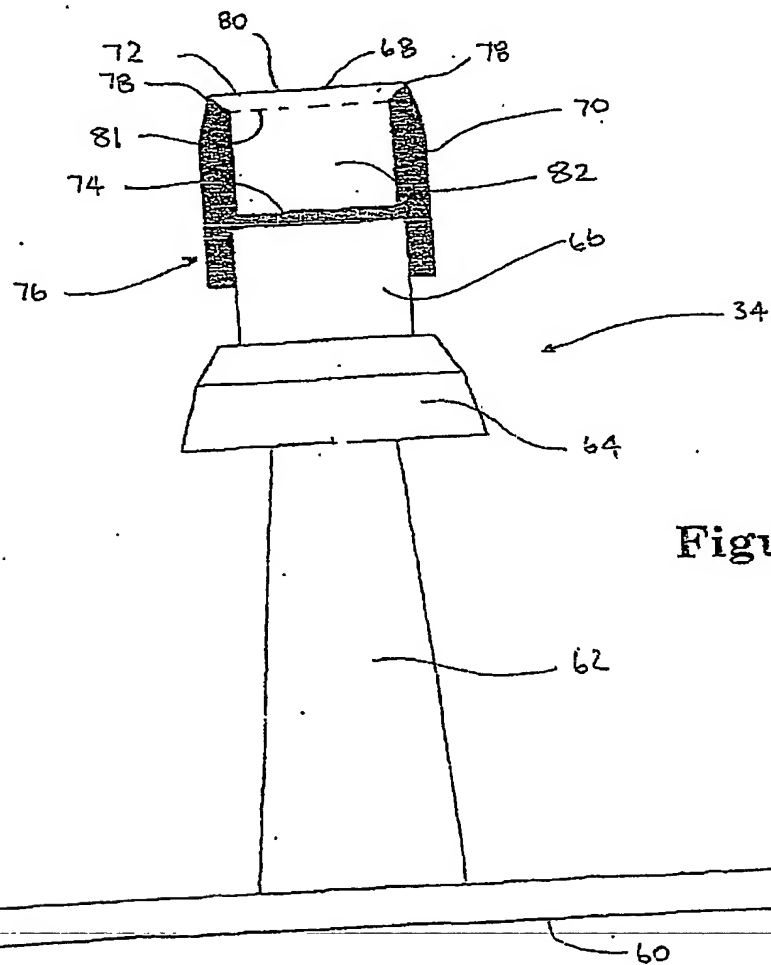


Figure 7

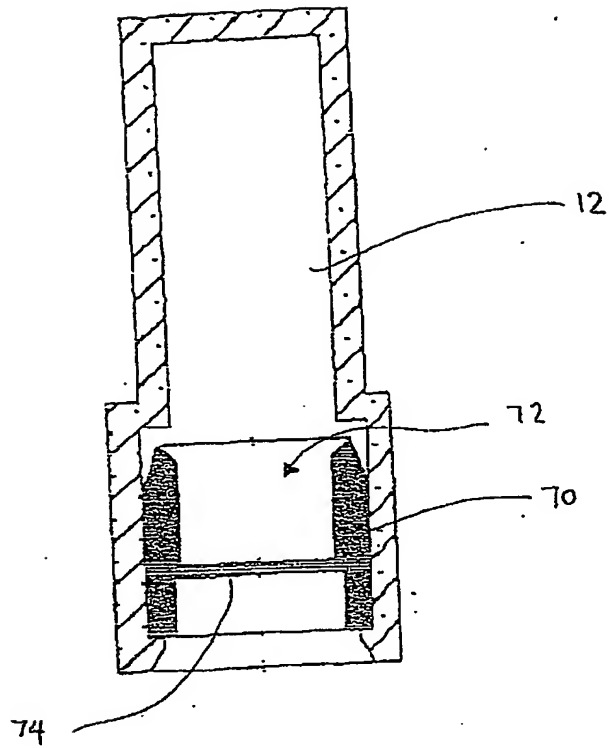


Figure 8

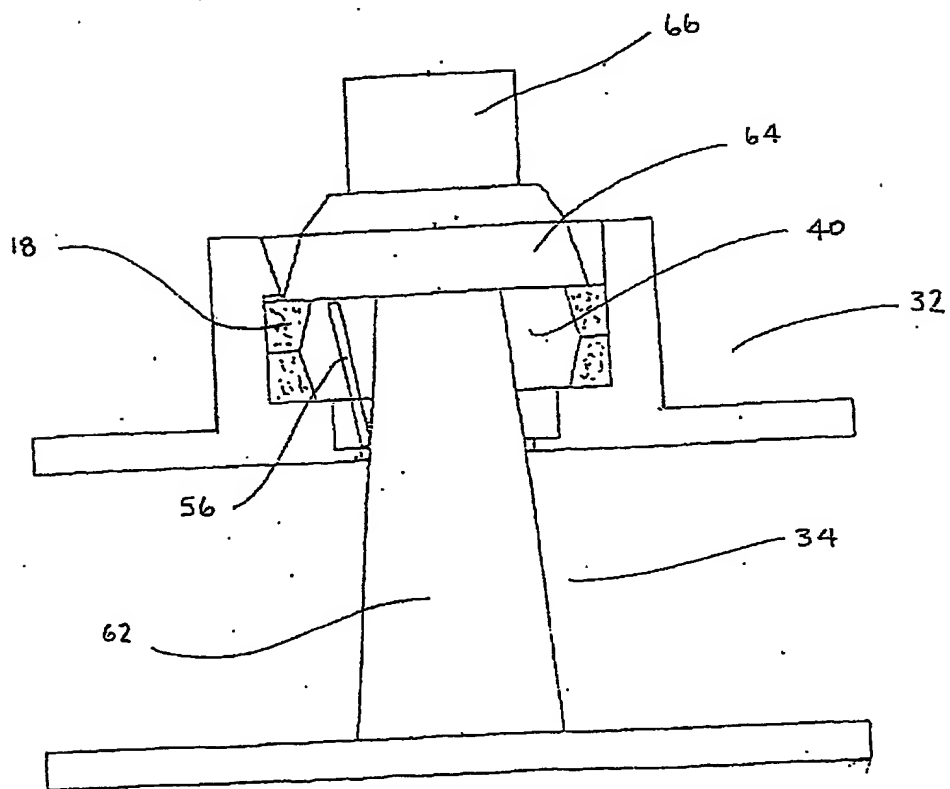


Figure 9

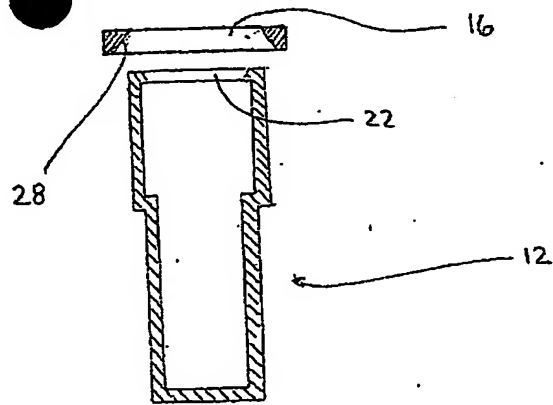


Figure 10a

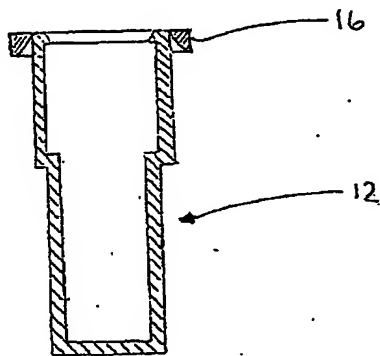


Figure 10b

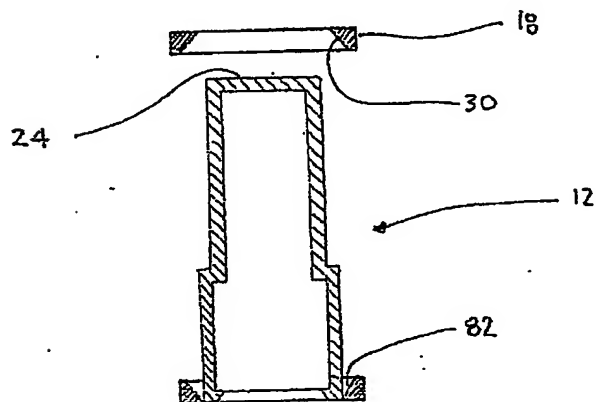


Figure 10c

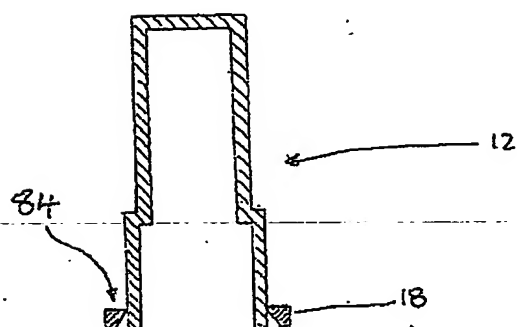


Figure 10d

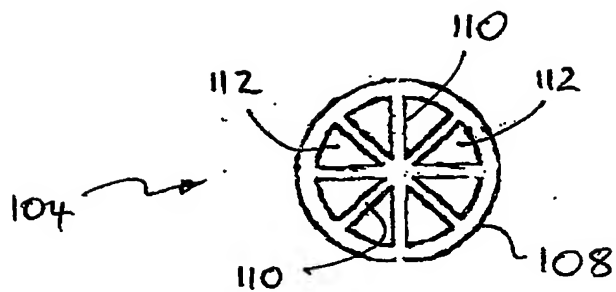


Fig. 11

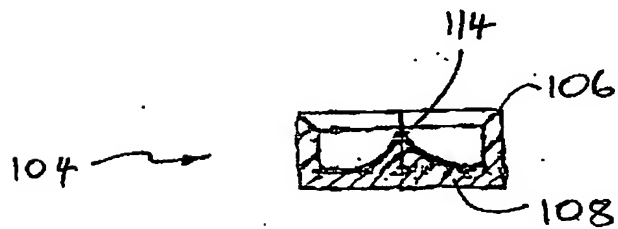
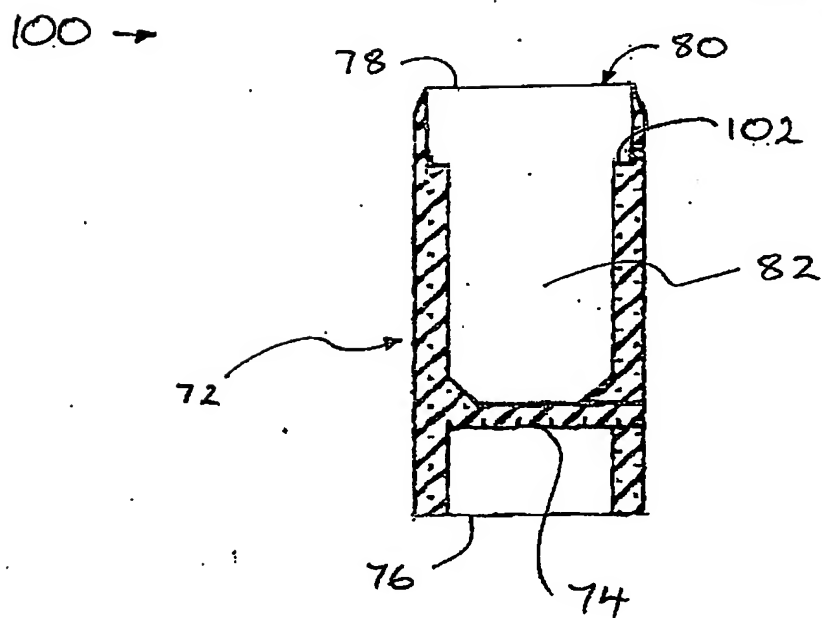


Fig. 12



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